

## Draft Notes from January 25, 2006 Immunization Advisory Committee Meeting

### **Framework for Establishing the Criteria**

John Stuart Mill in *On Liberty* wrote that “The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.” This thesis has become known as the harm principle. The Immunization Advisory Committee endorsed the harm principle and interpreted it to mean that vaccine mandates are justifiable when without them:

- An individual's decision could place others health in jeopardy
- The state's economic interests could be threatened by the costs of care for vaccine preventable illness, related disability or death and for the cost of managing vaccine preventable disease outbreaks
- The state's duty of educating children could be compromised

### **Assumptions for Establishing the Criteria**

The Immunization Advisory Committee made two assumptions while drafting criteria: (1) some kind of process exists for exemption from mandated immunization requirements in cases when vaccination is not appropriate (i.e. medical, religious, or philosophical reasons) and (2) that mandated vaccines were accessible to those for whom it is mandated

### **Draft Criteria**

The Immunization Advisory Committee grouped criteria into three categories: vaccine effectiveness, disease burden, and implementation. No recommendations were made on how many of these criteria needed to be met for a vaccine to be mandated nor were any decisions made as to how these criteria would be measured. The Committee requested that these criteria be drafted and tested against a vaccine to ensure that they were workable. The results will be reviewed by the committee at a third, yet unscheduled, meeting.

### **Criteria on the effectiveness of the vaccine**

***The vaccine must be recommended by the Advisory Committee on Immunization Practices and included on their recommended childhood immunization schedule.***

In other words, the vaccine must have been recommended by the USPHS the Advisory Committee on Immunization Practice (ACIP). The ACIP reviews licensed vaccines, and makes recommendations for newly licensed vaccines and regularly updates its recommendations. Their process includes (1) a review of the Food and Drug Administration (FDA) labeling/package inserts (label and unpublished, when available) on the safety, efficacy, acceptability, and effectiveness of the immunizing agent, with consideration of the relevance, quality, and quantity of published and unpublished data; (3) an assessment of cost effectiveness; (4) a review of the morbidity and mortality associated with the disease in the population in general and in specific risk groups; (5) a review of the recommendations of other groups; and (6) a consideration of the feasibility

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of vaccine use in existing child and adult immunization programs. Feasibility issues include (but are not limited to) acceptability to the community, parents, and patients; vaccine distribution and storage; access to vaccine and vaccine administration; impact on the various health care delivery systems; population distribution effects; and social, legal and ethical concerns.

### ***The vaccine must be effective.***

In the clinical development of a vaccine, the efficacy of the vaccine is studied in FDA approved research protocols and the question of whether or not the vaccine works is answered. In contrast, the effectiveness of the vaccine is determined by studying how well the vaccination prevents disease when used in “real world” clinical circumstance..

### ***The vaccine must be cost effective.***

Immunizations are the most cost-effective clinical preventive service for children, saving both lives and money. For a vaccine to be cost saving every dollar spent on preventing disease using the vaccine must yield savings that exceed the original investment. Vaccines may be cost –effective without being cost saving: that is, there is net cost of preventing disease and its associated direct costs (e.g., medical care, economic burden of disability or death and in some cases indirect costs (e.g., lost productivity of care takers of ill children) Not all vaccines recommended by the ACIP are cost saving or equally effective, so some determination of the vaccine’s relative cost effectiveness will be need to be made for comparison purposes.

### ***Experience to date with the vaccine must indicate that it is safe and has acceptable levels of side effects.***

Vaccinations are not without side effects. The risks of the preventive vaccination must be balanced against the risks of the disease. Health care providers are required by law to report certain adverse events and any one, may report any reaction or event thought to be related to receipt of a vaccine. These reports are entered into a national database (Vaccine Adverse Events Reporting System). The purpose of VAERS is to look for trends and pinpoint the need to investigate further.

### **Disease Burden Criteria**

#### ***The vaccine prevents diseases with significant morbidity and/or mortality implications.***

Vaccines have the potential to reduce or in some cases even eliminate diseases that can result in illness or death. For example, before the measles immunization was available, nearly everyone in the US got measles and an average of 450 measles-associated deaths were reported each year between 1953 and 1963.

#### ***Vaccinating the child must reduce the risk of spreading the disease to the community.***

Having a large percentage of the population vaccinated prevents the spread of certain infectious diseases. Even community members who are not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the

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disease has little opportunity to spread within the community. Vaccinating children in school and/or daycare centers can increase the percentage of children in these groups who are immune and thus reduce the risk of outbreaks of the disease in these groups and of its spreading to the community.

**Implementation Criteria**

***The vaccine must be acceptable to both the medical community and the public.***

It is possible to gauge the level of provider acceptance of the vaccine by querying state professional societies such as the Washington Academy of Family Physicians and the Washington State Chapter of the American Academy of Pediatrics. While there is generally good correlation between the levels of physicians' and the general public's acceptance of particular vaccines, a growing minority of the public has not accepted some recommended vaccines. Therefore, public acceptance of specific vaccines needs to be assessed.. Most parents today have never seen a case of diphtheria, measles, or other once-common diseases now preventable by vaccines. As a result, some parents wonder why their children must receive shots for diseases that seem no longer to exist in Washington communities. Myths and misinformation about vaccine safety abound and can make it difficult for parents who are trying to make sound decisions about their children's health care.

***The administration of the vaccine must be manageable.***

Many players are involved in the implementation of a vaccine mandate, including: the Department of Health, the Department of Social and Health Services, the Office of the Superintendent of Public Instruction, Local Health Jurisdictions, schools, health plans, and health care providers. For each of these key players, there are issues that affect the feasibility of implementing an immunization mandate. For example, the introduction of a new mandated vaccine can result in schools conducting more parental follow-up, and making changes to record and information systems - this in turn, can impact school staff workload.

***The cost to the parent/care giver must be within reasonable bounds.***

Parents/care givers are often involved in obtaining vaccines for their children. This can include: transporting children to medical appointments, taking time off of work for medical appointments, maintaining the child's immunization records, etc. When a vaccine is mandated it affects the health decisions that parents make on their child's behalf because parents must, at the very least, take the mandated vaccine into account.